Substitute f	or form 1449/PTO			Complete if Known		
				Application Number	09/553,969	
INFO	RMATION DIS	CLOS	URE	Filing Date	April 21, 2000	
STAT	<b>EMENT BY A</b>	<b>PPLIC</b>	ANT	First Named Inventor	WALLACE, DONALD G.	
				Art Unit	1611	
(	Use as many sheets as i	necessary)		Examiner Name	Lakshmi Sarada Channavajjala	
Sheet	1	of	7	Attorney Docket Number	017067-002040US	

			U.S. PATENT DO	CUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A26	US-2006-0167561 A1	07-27-2006	Odar et al.	
	A27	US-2009-0142396 A1	06-04-2009	Odar et al.	
	A28	US-2010-0028309 A1	02-04-2010	Odar et al.	
	A29	US-4,164,559	08-14-1979	Miyata et al.	
	A30	US-4,179,400	12-18-1979	Tsao et al.	
	A31	US-4,298,598	11-03-1981	Schwarz et al.	
	A32	US-4,362,567	12-07-1982	Schwarz et al.	
	A33	US-4,377,572	03-22-1983	Schwarz et al.	
	A34	US-4,600,574	07-15-1986	Lindner et al.	
	A35	US-4,640,834	02-03-1987	Eibl et al.	
	A36	US-5,162,430	11-10-1992	Rhee et al.	
	A37	US-5,209,776	05-11-1993	Bass et al.	
	A38	US-5,324,775	01-28-1994	Rhee et al.	
	A39	US-5,328,955	07-12-1994	Rhee et al.	
	A40	US-5,428,022	06-27-1995	Palefsky et al.	
	A41	US-5,510,418	04-23-1996	Rhee et al.	
	A42	US-5,520,925	05-28-1996	Maser	
	A43	US-5,580,923	12-03-1996	Yeung et al.	
	A44	US-5,614,587	03-25-1997	Rhee et al.	
	A45	US-5,667,839	09-16-1997	Berg	
	A46	US-5,690,675	11-25-1997	Sawyer et al.	
	A47	US-5,714,370	02-03-1998	Eibl et al.	
	A48	US-5,874,500	02-23-1999	Rhee et al.	
	A49	US-5,997,895	12-07-1999	Narotam et al.	
	A50	US-6,166,130	12-26-2000	Rhee et al.	
	A51	US-6,179,872	01-30-2001	Bell et al.	
	A52	US-6,312,474	11-06-2001	Francis et al.	
	A53	US-6,312,725	11-06-2001	Wallace et al.	
	A54	US-6,328,229	12-11-2001	Duronio et al.	
	A55	US-6,458,889	10-01-2002	Trollsas	

Signature Considered	

Substitute f	Substitute for form 1449/PTO				Complete if Known		
				Application Number	09/553,969		
INFO	RMATION DIS	CLOS	URE	Filing Date	April 21, 2000		
STAT	STATEMENT BY APPLICANT				WALLACE, DONALD G.		
				Art Unit	1611		
(	Use as many sheets as i	necessary)		Examiner Name	Lakshmi Sarada Channavajjala		
Sheet	2	of	7	Attorney Docket Number	017067-002040US		

				FOREIGN	PATENT DOCU	JMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Pate  Country Code <sup>3</sup>	ent Document  Number <sup>4</sup>	Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B10	EP	0612252	B1	05-12-1999	Naturin GmbH	English abstract	
	B11	EP	0891193		01-20-1999	Immuno AG		
	B12	EP	1084720	A1	03-21-2001	ED Geislich Sohne AG fur Chemische Industrie		
	B13	EP	1283063	A1	2/12/2003	ED Geistlich Sohne AG fur Chemische Industrie		
	B14	EP	1484070	A1	12/8/2004	Baxter International, Inc.		
	B15	JP	07090241		04-12-2007	Toshiba Corp.	English abstract	
	B16	wo	02/22184	A2	03-21-2002	Organogenesis Inc.		
	B17	WO	2002-070594	A2	09-01-2002	NY-Comed Pharma AS		
	B18	WO	2004/108179	A1	12/16/2004	Baxter International Inc. et al.		
	B19	WO	2006/031358	Α	3-23-2006	Hyberbranch Medical Technology, Inc. et al.		
	B20	wo	2006/118460	A1	11-9-2006	Suprapolix B.V. et al.		
	B21	WO	2007/001926	A2	1-4-2007	Hyberbranch Medical Technology, Inc. et al.		
	B22	wo	2007/137839	A2/A3	12/6/2007	BAXTER INT. INC.		
	B23	wo	2008/016983	A2	02-07-2008	Baxter Int. et al.		
	B24	wo	96/14368		05-17-1996	Izoret, Georges		
	B25	wo	97/37694	A1	10-16-1997	Immuno France SA et al.		
	B26	wo	99/13902	A1	03-25-1999	Integra Lifesciences Corp.	WO	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>

Examiner Signature Date Considered	
------------------------------------	--

Substitute fo	or form 1449/PTO			Complete if Known		
				Application Number	09/553,969	
INFOF	RMATION DIS	CLOS	URE	Filing Date	April 21, 2000	
STAT	STATEMENT BY APPLICANT				WALLACE, DONALD G.	
				Art Unit	1611	
(Use as many sheets as necessary)				Examiner Name	Lakshmi Sarada Channavajjala	
Sheet	3	of	7	Attorney Docket Number	017067-002040US	

		NON PATENT LITERATURE DOCUMENTS							
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>						
	C6	Barrow, D.L., et al.; "The Use of Greater Omentum Vascularized Free Flaps for Neurosurgical Disorders Requiring Reconstruction"; J. Neurosurg.; Vol. 60; pp 305-311 (Feb. 1984).							
	C7	Baxter product brochure for TissuFleece E, TissuCone E and TissuFoil E (2003).							
	C8	Baxter Product Catalogue; Collagen; 4 pages (2006).							
	C9	Chaplin, J.M., et al.; "Use of an Acellular Dermal Allograft for Dural Replacement: An Experimental Study"; Neurosurgery: Vol. 45:2; pp 320-327 (Aug. 1999).							
	C10	COLLINS, Ronald et al., "Use of Collagen Film as a Dural Substitute: Preliminary Animal Studies", Journal of Biomedical Materials Research, Vol. 25, 267-276 (1991).							
	C11	Filippi, R., et al.; "Bovine Pericardium for Duraplasty: Clinical Results in 32 Patients"; Neurosurg. Rev.; Vol. 20; pp 103-107 (2001).							
	C12	GentaFleece Kollagenvlies Version 5 found on internet at: http://www.advancingbiosurgery.com/en_EU/downloads/ifu_gentafleece.pdf, 3/2002, 2 pages.							
	C13	HIEB, Lee D. et al., "Spontaneous Postoperative Cerebrospinal Fluid Leaks Following Application of Anti-Adhesion Barrier Gel", SPINE volume 26, No. 7, pp. 748-751, 2001.							
	C14	KIM, Kee D., et al., "Reduction in Leg Pain and Lower-Extremity Weakness with Oxiplex/SP Gel for 1 Year after Laminactomy, Laminotomy, and Disectomy", Neurosurg Focus 17 (1): Clinical Pearl 1, July 2004, pp 1-6.							
	C15	Kline, D.G.; "Dural Replacement with Resorbable Collagen"; Arch Surg; Vol. 91; pp 924-929 (Dec 1965).							
	C16	Knopp U., "A new collagen foil versus a cadaveric dura graft for dural defects-a comparative animal experimental study", EANS- 12th European Congress of Neurosurgery, Lisbon, Sept. 7-12, 2003, 663-666.							
Examiner Signature		Date Considered							
Cignature		Official							

Substitute fo	or form 1449/PTO			Complete if Known		
				Application Number	09/553,969	
INFOF	RMATION DIS	CLOS	URE	Filing Date	April 21, 2000	
STAT	EMENT BY A	<b>PPLIC</b>	ANT	First Named Inventor	WALLACE, DONALD G.	
				Art Unit	1611	
(1	Use as many sheets as r	necessary)		Examiner Name	Lakshmi Sarada Channavajjala	
Sheet	4	of	7	Attorney Docket Number	017067-002040US	

		NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>					
	C17	KUHN, J. et al., "Bilateral Subdural Haemotomata and Lumbar Pseudomeningocele Due to a Chronic Leakage of Liquor Cerebrospinalis after a Lumbar Disectomy with the Application of ADCON-L Gel", J. Neural Neurosurg. Psychiarty 2005; 76: 1031-1033.						
	C18	Laquerriere, A., et al.; "Experimental Evaluation of Bilayered Human Collagen as a Dural Substitute"; J. Neurosurg; Vol. 78; pp 487-491 (Mar. 1993).						
	C19	LE, Anh X. et al., "Unrecognized Durotomy After Lumbar Discectomy: A Report of Four Cases Associated with the Use of ADCON-L", SPINE Volume 26, No. 1, pp 115-118, 2001.						
	C20	Lee, J.F., et al.; "Experimental Evaluation of Silicone-Coated Dacron and Collagen Fabric-Film Laminate as Dural Substitutes"; J. Neurosurg.; Vol. 27; pp 558-564 (Apr 1967).						
	C21	Matsumoto, K., et al.; "A Gelatin Coated Collagen-Polyglycolic Acid Composite Membrane as a Dural Substitute"; ASAIO Journal; pp 641-645 (2001).						
	C22	Maurer, P.K., et al.; "Vicryl (Polyglactin 910) Mesh as a Dural Substitute"; J Neurosurg; Vol. 63; pp 448-452 (Sep 1985).						
	C23	Meddings, N., et al.; "Collagen Vicryl- A New Dural Prosthesis"; Acta Neurochir; Vol. 117; pp 53-58 (1992).						
	C24	Mello, L.R., et al.; "Duraplasty with Biosynthetic Cellulose: An Experimental Study"; J Neurosurg; Vol. 86; pp 143-150 (Jan 1997).						
	C25	Narotam, P.K., et al.; "A Clinicopathological Study of Collagen Sponge as a Dural Graft in Neurosurgery"; J Neurosurg; Vol. 82; pp 406-412 (Mar 1995).						
	C26	Narotam, P.K., et al.; "Experimental Evaluation of Collagen Sponge as a Dural Graft"; British Journal of Neurosurgery; Vol. 7; pp 635-641 (1993).						
	C27	C27 O'Neill, P., et al.; "Use ofPorcine Dermis as Dural Substitute in 72 Patients"; J. Neurosurg.; Vol. 61; pp 351-354 (Aug 1984).						
Examiner Signature		Date Considered						

Substitute fo	or form 1449/PTO			Complete if Known		
				Application Number	09/553,969	
INFOF	RMATION DIS	CLOS	URE	Filing Date	April 21, 2000	
STAT	EMENT BY A	<b>PPLIC</b>	ANT	First Named Inventor	WALLACE, DONALD G.	
				Art Unit	1611	
(1	Use as many sheets as r	necessary)		Examiner Name	Lakshmi Sarada Channavajjala	
Sheet	5	of	7	Attorney Docket Number	017067-002040US	

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>					
	C28	Palm, S.J., et al.; "Dural Closure with Nonpenetrating Clips Prevents Meningoneural Adhesions: An Experimental Study in Dogs"; Neurosurgery; Vol. 45:4; pp 875-882 (Oct 1999).				
	C29	Parizek, J., et al.; "Detailed Evaluation of 2959 Allogeneic and Xenogeneic Dense Connective Tissue Grafts (Fascia Lata, Pericardium, and Dura Mater) Used in the Course of 20 Years for Duraplasty in Neurosurgery"; Acta Neurochir; Vol. 139; pp 827-838 (1997).				
	Park, Y-K., at al.; "Prevention of Arachnoiditis and Postoperative Tethering of the Spinal Cord with Gore-Tex Surgical Membrane: An Experimental Study with Rats"; Neurosurgery; Vol. 42 :4; pp 813-824 (Apr 1998).					
	C31	PCT International Preliminary Report on Patentability and Written Opinion mailed February 17, 2009, International Application No. PCT/US2007/074984, 8 pages.				
	C32	C32 Pietrucha, K.; "New Collagen Implant as Dural Substitute"; Biomatarials; Vol. 12; pp 320-323 (Apr 1991).				
	PORCHET, Francois, "Inhibition of Epidural Fibrosis with ADCON-L: Effect on Clinical Outcome One Year Following Re-operation for Recurrent Lumbar Radiculopathy", 1998, pp 1- 10.					
	C34	Raul, J.S., et al.; "Utilisation du Polyester Urethane (NEURO-PATCH®) Comme Substitut Dural"; Neurochirugie; Vol. 49:2-3; pp 83-89 (2003), <i>English abstract only on page 83</i> .				
	C35 Raul, J.S., et al.; "Utilisation du Polyester Urethane (NEURO-PATCH®) Comme Substitut Dural"; Neurochirugie; Vol. 49:2-3; pp 83-89 (2003).					
	C36 Reddy, M., et al.; "A Clinical Study of a Fibrinogen-Based Collagen Fleece for Dural Repair in Neurosurgery"; Acta Neurochir; Vol. 144; pp 265-269 (2002).					
	C37 ROSS, Jeffrey S. et al., "Association Between Peridural Scar and Recurrent Radicular PAIN After Lumbar Discectomy: Magnetic Resonance Evaluation", Neurosurgery, pp 855-863, 1996.					
	C38 San-Galli, F., et al.; "Experimental Evaluation of a Collagen-Coated Vicryl Mesh as a Dural Substitute"; Neurosurgery: Vol. 30:3; pp 396-401 (1992).					
Examiner		Date Considered				
Signature		Considered				

Substitute for form 1449/PTO				Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use as many sheets as necessary)				Application Number	09/553,969	
				Filing Date	April 21, 2000	
				First Named Inventor	WALLACE, DONALD G.	
				Art Unit	1611	
				Examiner Name	Lakshmi Sarada Channavajjala	
Sheet	6	of	7	Attorney Docket Number	017067-002040US	

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>						
	C39	Shaffrey, C.I., et al.; "Neurosurgical Applications of Fibrin Glue: Augmentation of Dural Closure in 134 Patients"; Neurosurgery; Vol. 26:2; pp 207-210 (1990).					
	C40	Smith, KA, et al.; "Delayed Postoperative Tethering of the Cervical Spinal Corei"; J Neurosurg; Vol. 81; pp 196-201 (Aug 1994).					
	C41	Springorum, H.W.; "Die Verwendung von Kollagenfolien zur Uberbruckung von Defekten des Gleitgewebes bei Achillotenotomien und Achillessehnenrupturen"; Akt. Traumata!.; Vol. 15; pp. 120-121 (1985), <i>English abstract only on page 120.</i>					
	C42	Springorum, H.W.; "Die Verwendung von Kollagenfolien zur Uberbruckung von Defekten des Gleitgewebes bei Achillotenotomien und Achillessehnenrupturen"; Akt. Traumata!.; Vol. 15; pp. 120-121 (1985).					
	C43	Stricker, A., et al.; "Die Verwendung von TissuFoil Membran bei der Sinusbodenaugmentation"; Ellipse; Vol. 17:1; pp 1-5 (2001), <i>English abstract only on page 1</i> .					
	C44	Stricker, A., et al.; "Die Verwendung von TissuFoil Membran bei der Sinusbodenaugmentation"; Ellipse; Vol. 17:1; pp 1-5 (2001).					
	C45	T. Kofidis et al., "Clinically established Hemostatis Scaffold (Tissue Fleece) as Biomatrix in Tissue- and organ-engineering research", Tissue Eng Vol 9, no. 3, 2003, S.517-523; ISSN: 1076-3279					
	C46 TissuFleece E found on internet at: http://www.biosurgery.de/Produkte/pdf/TissuFleece-E_GI.pdf, 02/2003, 2 pages.						
	Vinas, F.E., et al.; "Evaluation of Expanded Polytetrafluoroethylene (ePTFE) versus C47 Polydioxanone (PDS) for the Repair ofDura Mater Defects"; Neurological Research; Vol. 21; pp 262-268 (Apr. 1999).						
	C48 Warren, W.L., et al.; "Dural Repair Using Acellular Human Dermis: Experience with 200 Cases: Technique Assessment'; Neurosurgery; Vol. 46:6; pp 1391-1396 (Jun. 2000).						
	C49 Ziegelaar, B.W.; "Tissue Engineering of a Tracheal Equivalent", Doctoral Thesis at Ludwig Maximilians University, Munich, Germany; 25 pages (2004).						
Examiner Signature		Date Considered					

Substitute for form 1449/PTO				Complete if Known		
				Application Number	09/553,969	
INFOF	INFORMATION DISCLOSURE				April 21, 2000	
STATEMENT BY APPLICANT				First Named Inventor	WALLACE, DONALD G.	
				Art Unit	1611	
(	Use as many sheets as r	necessary)		Examiner Name	Lakshmi Sarada Channavajjala	
Sheet	7	of	7	Attorney Docket Number	017067-002040US	

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>		
	C50	Ziegelaar, BW et al., "The characterisation of human respiratory epithelial cells cultured on reabsorbable scaffolds: first steps towards a tissue engineered tracheal replacement", Biomaterials 23 (2002), 1425-1438; ISSN 0142-9612.			

Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of U.S. Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.